## ART 34 AMDT Rec'd PCT/PTO 28 APR 2005

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PACE 617. RCVD AT 1120249 AM Teastern Standard Truel Styling 120249. Onle Zdefogs. CSUS 239208 1900 Professor

Attorney Docket CSU-001M

We claim:

- 1. A method of modulating physiological and pathophysiological conditions mediated by androgens in a mammal, comprising the step of administering to the mammal an effective amount of an enantiomeric equal that can bind with free  $5\alpha$ -dihydrotestosterone, thereby inhibiting the binding of  $5\alpha$ -dihydrotestosterone with the androgen receptors in the mammal and mediating the conditions mediated by the androgen.
- 2. The method according to Claim 18Claim 1, wherein the physiological and pathophysiological conditions is selected from the group consisting of: benign prostatic hyperplasia, prostate cancer, male and female pattern baldness, facial and body hair, acne, excessive secretion of sebum from the sebaceous glands, skin effects, anti-aging, anti-photoaging, skin integrity, skin pigmentation, skin whitening, Alzheimer's disease, emotions and mental health, depression, anxiety, Tourette's disease, Kennedy's syndrome, congenital defects in steroidal hormone synthesis and metabolism involving androgens, obesity, body weight, lipid and cholesterol levels, lipogenesis, lipolysis, inhibiting insulin resistance, blood pressure, thyroid function, and cardiovascular disease.
- 3. The method according to Claim 1 wherein the equal is administered as an oral composition comprising at least 1 mg enantiomeric equal.
- 4. The method according to Claim 1 wherein the equal is administered as a topical composition comprising at least 0.1% enantiomeric equal.
- 5. The method according to Claim 1, wherein the equal is administered as a composition comprising essentially an R-equal enantlomer.
- 6. The method according to Claim 1 wherein the equal is administered as a composition comprising a non-racemic mixture of R-equal and S-equal enantiomers.

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- 7. A method of treating and preventing an androgen-related disease in a mammal, comprising the step of administering to the mammal an effective amount of an enantiomeric equal that can bind with free 5α-dihydrotestosterone, thereby inhibiting the binding of the 5α-dihydrotestosterone with the androgen receptors in the mammal.
- 8. The method according to Claim 7, wherein the androgen-related disease is selected from the group consisting of: benign prostatic hyperplasia, prostate cancer, male and female pattern baldness, facial and body <u>hair</u>, acne, excessive secretion of sebum from the sebaceous glands, skin effects, anti-aging, anti-photoaging, skin integrity, skin pigmentation, Alzheimer's disease, abnormal emotions and mental health, depression, anxioty, Tourette's disease, Kennedy's syndrome, congenital defects in steroidal hormone synthesis and metabolism involving androgens, obesity, abnormal body weight, abnormal lipid and cholesterol levels, excessive lipogenesis, lipolysis, inhibiting insulin resistance, high blood pressure, thyroid function, and cardiovascular disease.
- 9. The method according to Claim 7, wherein the equal is administered as a composition comprising essentially an R-equal enantiomer.
- 10. The method according to Claim 7 wherein the equal is administered as a composition comprising a non-racemic mixture of R-equal and S-equal enantiomers.
- 11. The method according to Claim 7 wherein the equal is administered as an oral composition comprising at least 1 mg enantiomeric equal.
- 12. The method according to Claim 7 wherein the equal is administered as a topical composition comprising at least 0.1% enantiomeric equal.
- 13. The method according to Claim 12 wherein said composition does not comprise a significant amount of any other androgen-receptor binding compound.
- 14. A method of modulating androgen hormone activity in a mammal, comprising the step of administering to the mammal an effective amount of an enantiomeric equal

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that can bind with free  $5\alpha$ -dihydrotestosterone, thereby modulating the binding of  $5\alpha$ -dihydrotestosterone with the androgen receptors in the mammal.

- 15. A method of preventing DHT binding to the AR by contacting the DHT with an enantiomeric equal prior to the binding of DHT and AR.
- 16. A method according to Claim 15 wherein the contacting occurs in vivo in a mammal.
- 17. A method of treating and preventing a combination of an androgen-related condition and an estrogen-related condition in a mammal, comprising the step of administering to a mammal an effective amount of a mixture of R-equol and S-equol, that can bind with free  $5\alpha$ -dihydrotestosterone, and with free  $5\alpha$ -dihydrotestosterone and the estrogen receptor, respectively, thereby inhibiting the binding of the  $5\alpha$ -dihydrotestosterone with the androgen receptors, and affecting binding of the estrogen receptors.
- 18. A method of modulating age-related androgen/estrogen hormonal balances, comprising the steps of:
  - a. determining a mammal's endocrine androgen/estrogen hormone balance,
- b. administering to the mammal an effective amount of a mixture of R-equol and S-equol, that can modulate the hormone balance of  $5\alpha$ -dihydrotestosterone and estrogen.
- 19. The use of an enantiomeric equal to bind in vivo free DHT, for modulating physiological and pathophysiological conditions mediated by androgens in a mammal.
- 20. A method of regulating the level of LH *in vivo* in a mammal by contacting the DHT of the mammal with enantiomeric equal.
- 21. The use of enantiomeric equol as a diagnostic agent for physiological and pathophysiological conditions mediated by androgens/androgen-related disorders effected by an estrogenic/androgenic imbalance.



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22. The use of equal in a competitive binding assay, the assay comprising the steps of:

- 1) providing an androgen receptor,
- 2) providing a complex of DHT-enantiomeric equol,
- 3) providing a test substance comprising an androgen binding moiety, and
- 4) contacting and competing for the DHT-enantiomeric equol complex.